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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,178	01/13/2004	Fred H. Burbank	R0367-00702	2089

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/756,178

Applicant(s)

BURBANK ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 19-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 19-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/13/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/24/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Priority

It is noted that in addition to the applications recited in the Cross Reference to Related Applications section of the specification there are numerous other co-pending applications which disclose and claim very similar and/or identical subject matter. In accordance with MPEP 704.11(a) subsection G, applicant is respectfully requested to disclose all co-pending applications and related patents and identify the specific claims of those applications and/or patents which may present double patenting issues with the instant application claims.

Specification

The disclosure is objected to because of the following informalities: the Related Applications section should be updated to provide the most current status (i.e. US Patent Number or "abandoned") of the related applications.

Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the device having a tissue separator/isolator, an encapsulation means and a damaging means must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21 and 25-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The application, as originally filed, failed to disclose the specific combination of steps including separating a tissue specimen, encapsulating the separated tissue and damaging the separated tissue specimen as now set forth in independent claim 19. Also, the specification does not

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disclose a device including separate tissue cutting, tissue encapsulating and tissue damaging devices as now set forth in independent claim 30.

While the instant specification has been amended to include subject matter from related US Patent No. 6,344,026 directed towards a tissue encapsulation device, there is nothing in the instant disclosure or any of the other related documents to support the cutting/separation, encapsulation and damaging of tissue. The instant specification as originally filed (i.e. without the subject matter of the '026 patent incorporate therein) discloses only the cutting/separation of tissue with the subsequent damaging of the tissue. Page 10 of the specification indicates that Figure 6 shows a "tissue specimen isolating and damaging device" that has a morcellator to morcellate tissue. The specification then states "The tissue specimen may be morcellated after encapsulation of the tissue specimen." This is the only support found that suggests that all three modalities (i.e. separation, encapsulation and damaging) may be performed in the same procedure. However, there is no specific description of how the encapsulation is performed using the tissue isolating and damaging device as shown in Figure 6. The tissue encapsulation device of Figures 9 and 10 fails to disclose a tissue separating and/or tissue damaging means. It seems the only logical way to provide the three separate treatment modalities based on applicant's disclosure would be to insert the device of Figure 6 to isolate/cut tissue, remove that device, insert the device of Figure 9 to encapsulate the tissue, remove that device, then re-insert the Figure 6 device to morcellate/damage the tissue. However, there is no disclosure of such a series of steps,

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and it seems counterintuitive to the process that allows for the treatment and removal of biopsy tissue with a single device.

It is noted that other related US Patents, such as US Patent No. 6,331,166, indicates that encapsulation of tissue is an alternative treatment to the isolation and damaging of tissue (see Abstract). Also, US Patent No. 6,344,026, which is the subject matter incorporated into the instant specification to provide support for the encapsulation embodiments of Figures 9 and 10, does not disclose the isolation and/or damaging of tissue as now recited in the instant application claims. There is no suggestion in the instant application description or in any of the related applications and patents that all three modalities (isolation, encapsulation and damaging) are performed in the same procedure with the same device.

It is further noted that US Patent Numbers 6,659,105 and 6,676,658 (from which the instant application is a direct continuation) suggest alternative embodiments where "the tissue specimen is damaged by encapsulation" or "the tissue may be physically isolated by encapsulation". This recitation merely implies that two modalities are one and the same, and does not provide explicit support for performing three separate steps with three separate means as is now recited in claims 19-21 and 25-39.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kresch et al (5,527,331).

Kresch et al provide a device for isolating and damaging a tissue specimen. The device is inserted into tissue, and a wire cutting element (202 – Figure 9) is used to isolate tissue. The tissue is then damaged by morcellator (206). The arcuate cutting element (202) is also an RF electrode (col. 10, lines 50+).

Claims 1 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Savage et al (6,032,673).

Figure 9 of the Savage et al device is identical to the above discussed Kresch et al system. It includes an arcuate, RF electrode loop (202) for isolating tissue and a rotating morcellator (206) to damage the tissue.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,659,105.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the narrower claims of the '105 patent would necessarily infringe on the more broadly recited method steps in the instant application.

Claims 1 and 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,676,658.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the apparatus claims of the '658 patent would necessarily infringe on the more broadly recited method steps in the instant application and would inherently be used in the same method.

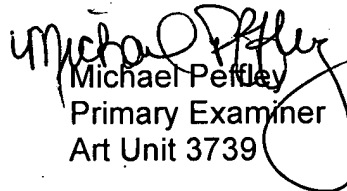
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Perley
Primary Examiner
Art Unit 3739

mp
March 29, 2006